DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Roesys GmbH
% Mr. Jochen Dyszbalis
Quality Manager
Dr.-Max-Ilgner-Str. 2
Espelkamp, Nordrhein-Westfalen 32339
GERMANY

December 3, 2014

Re: K133496
Trade/Device Name: X Twin System
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: KPR
Dated: October 22, 2014
Received: October 24, 2014

Dear Mr. Dyszbalis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K133496

Device Name
X Twin System

Indications for Use *(Describe)*
The X Twin is intended to be used as a digital multifunctional x-ray system, suitable for all radiographic exams, including specialist areas like trauma or pediatric work, excluding mammography.

X Twin shall only be operated by qualified, trained professionals. The patient can be in sitting, lying or standing position.

The device is a permanently installed device and is intended to be operated in medical rooms with appropriate radiation protection only. It is not intended to be used with flammable anesthetic agents or in potentially explosive atmospheres.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Name and Address of manufacturer:

Roesys GmbH
Dr.-Max-Ilgner-Straße 2
32339 Espelkamp
Germany

Owner/Operator Number: 10045270

Name, title and phone number of official correspondent:
Jochen Dyszbalis
Quality Manager
+49 5772 91555 00

Date of preparation: November 11, 2013

Device Identification:

Device Trade Name:	X Twin
Common Name:	General purpose diagnostic X-ray unit

Classification of the device:

Device Classification Name:	System, X-ray, Stationary
Product Code:	KPR
Device Classification No.:	Part 892.1680
Panel:	Radiology
Regulatory Status:	Class II

Predicate device:

Device Trade Name:	Essenta DR
Applicant:	Philips Medical Systems DMC GmbH
510(k) No.:	K070528

Device Description:

X Twin

The X Twin is a digital multifunctional x-ray system, in which an X Twin stand holds the x-ray image receptor, the collimator and the x-ray tube including the x-ray tube housing

assembly. The generator, x-ray tube, beam limiting device, image receptor, including the workstation for image processing plus imaging software and the optional mobile x-ray table are known components. The geometry of the X Twin contains two guide frames, two support arms, an x-ray tube column and an image receptor column. The movements of the columns and the arms as well as the SID adjustment are motorized. The x-ray tube support arm as well as the image receptor support arm is provided with an integrated control unit, located at the front of the support arms. These units allow an adjustment of angle, height and distance of the image receptor and x-ray in relation to the patient. Simultaneously an integrated electronic control system provides automatic focusing of the image receptor and x-ray tube. Additionally an integrated touch display for indication of current values and additional control options is implemented in the tube support arm. The device receives its power from the x-ray generator.

Imaging Device

An essential part of the X-ray system X Twin is the digital Flat Panel Image Detector. In the X Twin System is mounted the Digital X-ray Detector DFP4343C7. The Digital X-ray Detector DFP4343C7 is a medical image processing unit. Especially, advanced digital imaging process allows considerably efficient diagnosis, all kind of information management, real-time sharing of image information on network. DFP4343C7 is a high-resolution digital imaging detector, designed for general radiography. The X-ray Conversion Layer consists of Cesium Iodide (Csl) with Amorphous Silicon (a-Si) Photodiode. The active area has a size of 430(H)×439(V)mm (16.9×17.3 inch), the Pixel Matrix has a size of 3008(H)×3072(V) with a Pixel Pitch of 143 µm.
The Cycle Time from Shot to Shot is 6sec.
The Digital X-ray Detector DFP4343C7 is released by the FDA in a 510 (k) process. The Release Number is K122589.

Software

The software used in the X Twin consists of two systems:

- **X Twin Control Software**
  The X Twin Control Software controls only the motorized adjustment of angle, height and distance of the image receptor and x-ray in relation to the patient. These movements are only possible if corresponding switches are manually operated. When the switch is released, the movement is stopped immediately. Simultaneously an integrated electronic control system provides automatic focusing of the image receptor and x-ray tube. This function is also only possible during manually operated switches.
  The angle and the SID is displayed on the control unit on the support arm of the X Twin. The control software controls also the emergency stop buttons ant the collision protection of the X Twin. The control software neither provides automatically movement actions nor does it take influence on the diagnosis.
  Failures or latent design flaws are unlikely to cause any injury to the patient or operator. In accordance to the Guidance for Software used in Medical Devices Roesys has determined the Level of Concern of the X Twin Control software as Moderate.

- **Imaging Software DXRS**
  DXRS software is intended for acquisition, processing, viewing, printing, saving and transmittance of X-ray images to PACS server. DXRS software can retrieve patient data from other information systems (HIS/RIS).
  DXRS software includes a main application (below referred to as SW application), its modules and utilities. SW application provides declared functionality. Modules and utilities provide additional functionality.
  Brief description of the operation scenario
  Operation scenario includes a sequence of actions described below.
  Manual input of patient data or its automatic retrieval using Worklist function.
  Acquisition of X-ray image by the detector manufacturer's service software, supplied with the detector. SW application displays recommended values of exposure parameters which operator can use to acquire an X-ray image of a specific body part. Recommended values are only displayed and do not define or influence exposure process in practice in any way.
  Image processing is carried out manually to prepare images for diagnostics. Image processing includes zoom, navigation, flip and rotation, inversion, usage of collimators (program shutters) and adjustment of Window Width/Level. SW application also provides lateralization and a rollback function which removes results of actions applied to the image and brings image back to the initial state. As a result of post-processing operations, the image is ready to be displayed or to be used for diagnostic purposes.
  Sending acquired X-ray images to a PACS server for storage
  Printing images or creation of Patient Disks (if necessary)
  In accordance to the Guidance for Software used in Medical Devices the Level of Concern for our device is Moderate. DXRS Software and the accompanying Digital X-Ray Detector DFP4343C7 are designed only for general radiographic systems. They are used neither in X-ray surgery nor mammography nor in life supporting systems.
  The DXRS software was part of the 510(k) Premarket Notification No. K122589.

Intended Use:
The X Twin is intended to be used as a digital multifunctional x-ray system, suitable for all radiographic examinations including specialist areas like trauma or pediatric work, excluding mammography.
X Twin shall only be operated by qualified, trained professionals. The patient can be in sitting, lying or standing position.
The device is a permanently installed device and is intended to be operated in medical rooms with appropriate radiation protection only. It is not intended to be used with flammable anesthetic agents or in potentially explosive atmospheres.

Table 1: Substantial Equivalence Chart

	Substantial Equivalent Device	Predicate Device	
	X Twin	**Essenta DR (K070528)**	
Intended Use	The X Twin is intended to be used as a digital multifunctional x-ray system, suitable for all radiographic exams, including specialist areas like trauma or pediatric work, excluding mammography. X Twin shall only be operated by qualified, trained professionals. The patient can be in sitting, lying or standing position. The device is a permanently installed device and is intended to be operated in medical rooms with appropriate radiation protection only. It is not intended to be used with flammable anesthetic agents or in potentially explosive atmospheres.	The ESSENTA DR is a digital multifunctional X-ray system, suitable for all routine radiographic exams, including specialist areas like trauma or pediatric work, excluding mammography. It is designed for radiographic examination of the standing or seated patient or the recumbent patient in combination with a mobile x-ray table (trolley). The system is intended for direct digital imaging using the built in flat panel detector and in addition for free exposures on radiographic cassettes.	Similar
Target population	Adult and pediatric subjects	Adult and pediatric subjects	Equivalent
Operator	Qualified trained professionals	Qualified/trained doctor or technicians	Equivalent
Energy Source	400 V / 480 V ± 10%, 50/60 Hz	400 V / 480 V ± 10%, 50/60 Hz	Equivalent
Power consumption	24 - 44 kVA	50 - 80 kVA	Advanced, the power consumption is reduced, but the X-Ray parameters are similar
Maximum output	Depends on chosen generator model.	Depends on model of generator chosen. Models are available from 50 kW to 80 kW.	Equivalent
User Interface	Software Driven Touch Panel LCD + two individual control units located at each support arm (one is a wired remote control)	Software Driven Touch Panel LCD, + remote control unit	Similar
Columns	Two columns (tube & receptor). Guide frame mounted on floor	One main column. Floor or wall mounted support	Different, but does not concern safety or efficacy
Tube mount	Fixed to a tube column, arm can rotate Automatic focusing by an integrated control system	Fixed with respect to receptor, arm can rotate	Advanced

Receptor mount	Fixed to a receptor column, arm can rotate Automatic focusing by an integrated control system	Fixed on same column as tube head	Difference: Fixed to a separate column; Does not concern safety or efficacy
Method of control	Software Driven Touch Panel LCD, + two individual control units located at each support arm (one is a wired remote control)	Software Driven Touch Panel LCD, + remote control unit + Detector control unit	Similar
Electrical safety	IEC 60601-1	IEC 60601-1	Equivalent
Source-to-image distance (SID)	vertical: 40 -110 cm (16-44”) horizontal: 100-200 cm (40-79”) (also continuously adjustable and dual speed motorized)	110-200 cm (43-79”) continuously adjustable (dual speed motorized movement)	Advanced
Vertical travel	1,600 mm (63”)	1,330 mm (4’ 4.4”)	Equivalent
Longitudinal travel	100 cm (40”) (each column)	None	Advanced
Rotation angle	± 100° (each arm)	-30° to +135°	Different, but does not concern safety or efficacy
Total weight	175 kg +410 kg = 585 kg (1x 1290 lb) (Guide frame with column + Vertical pillar)	300 kg (661.5 lb)	Different, but does not concern safety or efficacy
Image Detector	Electronic flat detector with High Stability Scinitillator Active detector area: 35 cm x 43 cm (14” x 17”) with rotatable detector carrier Image matrix size: 1920 pixel x 2367 pixel Pixel size: 182 µm, with a pixel depth of 14 bits	Flat Panel Detector with Cesium Iodide (CsI) for X-ray scintillator Active detector area: 43 cm x 43 cm (16.9″ x 17.3″) with rotatable detector carrier Image matrix size: 3008(H) pixel x 3072(V) pixel Pixel size: 143 µm, with a pixel depth of 14 bits	Different, but does not concern safety or efficacy

Detailed description of the main differences between X Twin and the predicate Essenta DR:

Power consumption: The power consumption of the X Twin is lower than of the predicate Essenta DR (24-44 kVA against 50-80 kVA).
This means that the twin X has better energy efficiency. The X-Ray parameters are similar with the parameters of the Essenta DR, therefore the difference does not concern safety or efficacy.

Columns: The difference of both systems is that the X Twin contains two moveable columns and the Essenta DR has only one column.
The columns of the X Twin are motorized, positioned on floor mounted guide frames. The column of the Essenta DR is fix floor or wall mounted. The advantage of the X Twin is a higher flexibility for the positioning of the system. Since the X-Ray imaging process is not affected from this difference, it does not concern safety or efficacy.

Tube and Receptor Mount: The main difference in mounting the tube and the receptor is that these components are fixed on an adjustable U-arm at the Essenta DR. The X Twin uses separate arms, one for the tube and one for the receptor. This allows the occasionally necessary recording with a beam path which is not aligned at 90° to the Receptor. The advantage of the X Twin is a higher flexibility for the positioning of the system. Since the X-Ray imaging process is not affected from this difference, it does not concern safety or efficacy.

Rotation Angle: Both X-Ray systems have different rotation angles. The Essenta DR has a rotation angle range of 165°, the X Twin has a rotation angle range of 200° (applicable for standard images: 180°). The advantage of this difference is a higher flexibility for a wide range of examinations. Since the X-Ray imaging process is not affected from this difference, it does not concern safety or efficacy.

Total Weight: The total weight of the X Twin is higher than the total weight of the Essenta DR (difference: 285 kg / 628.5lb). The reason for this difference is the second column with the second arm and the floor mounted guide frames. Since these units are floor mounted, this difference does not concern safety or efficacy.

Image Detector: There are two differences between the used Image Detectors. The first difference is the active detector area. The Predicate Essenta DR uses a 14” x 17” detector; the X Twin uses a 16.9″ x 17.3″ detector. This has the advantage that even large organs such as thorax can be recorded on one image.
The second difference is the higher pixel resolution (Predicate 182 µm – X Twin 143 µm). This allows the creation of images with higher resolution. An illustration of finer tissue structures is thus more feasible.

These main differences do concern safety or efficacy of the X Twin System neither individually nor in combination with each other.

Summary of Non-Clinical Performance Testing:

IEC 60601-1
IEC 60601-1-2
IEC 60601-1-3

Test clauses:
7.6 Test for half-value layer
8.5.2 Focal spot to image receptor distance
12.4 Leakage radiation

IEC 60601-2-54
ISO 10993

Result of the biocompatibility Tests:
There was no evidence found that the surfaces of the X Twin system may cause skin irritations or similar negative effects on the patient. The observed surface coatings are used on similar medical devices for 10 years, during this time was no case regarding skin irritation was known.

Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices

The documentation and testing of the X Twin Control Software was classified and performed as Moderate in accordance to the Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.

The documentation and testing of the Imaging Software DXRS was also performed in accordance to the Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices. This software is part of the Image Detector DFP4343C7, therefore the software is already released (see K122589).

Regarding the Image Detector DFP4343C7 a separate Non-Clinical performance testing was performed by NIPK Electron as 510(k) Applicant.
The performance testing was performed according to Section VI of the Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices.
All test results were satisfactory.

Summary of Clinical Performance Testing:

Roesys GmbH did not perform any clinical testing for the X Twin.

Regarding the Image Detector DFP4343C7 a Clinical Performance Testing was performed by NIPK Electron as 510(k) Applicant.
The performance testing was performed according to Section VII of the Guidance for the Submission of 510(k)’s for Solid State X-ray Imaging Devices.
All test results were satisfactory.

Conclusion:
Roesys GmbH believes that the X Twin system is substantially equivalent to the currently legally marketed device. It does not introduce new indications for use, has the same technological characteristics and does not introduce new potential hazards or safety risks.